

REMARKS/ARGUMENTS

Reexamination and reconsideration of this application, withdrawal of the rejections, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above amendments and remarks that follow.

Claims 1-13 and 15-27 are pending in the application. Claim 1 has been amended herein to recite that the polymeric structure is in the form of a hydrogel that swells in water. Support for this amendment may be found throughout the specification, such as on page 5 (paragraph 23) and page 6 (paragraph 27). It is respectfully submitted that no new matter has been introduced by this amendment.

Applicants note that the Examiner considers new Claims 25-27 to be withdrawn as directed to a non-elected invention. Applicants respectfully request reconsideration of the restriction requirement as applied to those claims. All three claims depend from Claim 1 and, thus, include all limitations in independent Claim 1. It is not believed that additional search and examination of these claims would be unduly burdensome to the Examiner. Even if the decision is made to currently maintain these claims as withdrawn, Applicants respectfully request consideration of these claims for rejoinder upon allowance of independent Claim 1, as set forth in MPEP §821.04.

Claims 1-13, 17-19, and 22-24 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,607,687 to Bezwada *et al.* The Examiner relies upon the Bezwada patent as teaching compositions comprising PEG polymers and coupling agents. Applicants respectfully traverse this rejection.

The pending claims have been amended to clarify that the cross-linked polymeric structure embodied in the claims is in the form of a hydrogel that swells in water. Such a polymeric form is simply not contemplated by the Bezwada reference, and one of ordinary skill in the art would not view the Bezwada reference as teaching or suggesting such a structure.

The present invention is directed to chemically crosslinked degradable PEG hydrogels capable of exhibiting a controlled degradability. Weak chemical linkages are introduced into the hydrogel and provide for the hydrolytic degradation of the crosslinks and the release of drug molecules that can be trapped within the hydrogel. The hydrogels degrade to substantially non-toxic PEG fragments which are usually cleared from the body.

In contrast, the Bezwada patent is directed to polymer blends that can be melt processed into various medical and surgical devices, such as wound closure devices. There is not even a single mention of a hydrogel in the Bezwada reference. Instead, the Bezwada reference clearly indicates that substantial crosslinking of the polymers described therein, such as would be expected in a hydrogel-forming structure, is undesirable. At the bottom of column 4, the reference expressly states that the amount of coupling agent “to be added before gelation occurs” is a function of the type of coupling agent and the polymerization conditions (lines 65-67). This is a clear indication that the Bezwada reference does not envision gelation at all and instead intends for the coupling agent to be present in amounts small enough to avoid extensive crosslinking throughout the polymer structure, as would be expected in a hydrogel. The only noted function for the coupling agents is to “cause the branching of long chains,” which the reference states can “impart desirable properties in the molten state” to the polymer (column 4, lines 57-60) (emphasis added). Thus, the only purpose for the coupling agent is to cause branching of long chains in order to adjust the properties of the polymer while molten. One of skill in the art would recognize that branching within a polymer structure is not equivalent to crosslinking. Branching merely refers to the side chains of a polymer main chain, while crosslinking occurs when adjacent polymer chains are connected by a crosslinking moiety. This difference is important because crosslinking would be expected to severely hinder melt processing of polymer blends, which is a stated goal of the Bezwada reference. In sum, the reference cited by the Examiner: (1) requires the polymers taught therein to be melt processable; (2) specifically mentions the use of coupling agent before gelation occurs; and (3) does not mention crosslinking or hydrogel structures at all.

These facts negate any reasonable view of the Bezwada patent as anticipatory. An anticipatory reference must describe the claimed invention “with sufficient precision and detail to establish that the subject matter existed in the prior art.” *Verve LLC v. Crane Cams Inc.*, 65 USPQ2d 1051, 1054 (Fed. Cir. 2002). As also noted by the Federal Circuit, an anticipatory reference must “describe the applicant’s claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it.” *In re Spada*, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). In the present rejection, the cited reference does not even mention hydrogel formation, whereas the pending claims recite a polymer structure in the form of a

hydrogel. Accordingly, Applicants respectfully submit that the cited art fails to teach each and every limitation of the claimed invention, and therefore request that the Examiner reconsider and withdraw this rejection.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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